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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 09/688,017  | 10/13/2000  | Peter S. Lu          | 20054-001110US        | 7473             |
| 20350   | 7590        | 04/06/2004           | EXAMINER              |                  |
| TOWNSEND AND TOWNSEND AND CREW, LLP<br>TWO EMBARCADERO CENTER<br>EIGHTH FLOOR<br>SAN FRANCISCO, CA 94111-3834 |             |                      | BELYAVSKYI, MICHAIL A |                  |
|   |             | ART UNIT             | PAPER NUMBER          |                  |
|   |             | 1644                 |                       |                  |

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                      |              |
|------------------------------|----------------------|--------------|
| <b>Office Action Summary</b> | Application No.      | Applicant(s) |
|                              | 09/688,017           | LU ET AL.    |
|                              | Examiner             | Art Unit     |
|                              | Michail A Belyavskyi | 1644         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 28 January 2004.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 23-25,38-40 and 42 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 23-25,38-40 and 42 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/28/04 has been entered.

Claims 23-25, 38-40 and 42 are pending.

*Claims 23-25, 38-40 and 42 read on a method for determining an interaction profile for a PDZ ligand protein under consideration in the instant application.*

2. The rejection under 35 U.S.C. 103 (a) as being unpatentable over Gee et al., in view of the know fact disclosed in the Specification on page 53 and further in view of the Coligam et al is hereby withdrawn in view of the amendment to claim 23. However, this rejection will be reintroduced when the **new matter** (determining an interaction profile for PL protein) is deleted from claim 23.

The following new ground of rejections are necessitated by the amendment filed 01/28/04

3. The following is a quotation of the second paragraph of 35 U.S.C. 112.  
*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

4. Claims 23-25, 38-40 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is indefinite and ambiguous in the recitation of "determining an interaction profile". The characteristics and metes and bounds of "determining an interaction profile" are unclear, indefinite and not defined by the Specification.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23-25, 38-40 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

“ Determining an interaction profile for PDZ ligand protein (PL) , comprising a step of determining an interaction profile for the PL protein from the interaction detected in step (b) claimed in claim 23 represent a departure from the specification and the claims as originally filed. The passages pointed by the applicant do not provide a clear support for “Determining an interaction profile for PDZ ligand protein (PL) , comprising a step of determining an interaction profile for the PL protein from the interaction detected in step (b) .

The specification and the claims as originally filed only support a method for identifying an interaction between a PDZ domain containing polypeptide and PDZ ligand protein (PL) comprising:

- a) contacting the PL protein to an array of at least 5 PDZ-domain polypeptides
- b) detecting binding of the PL protein to one or more of the PDZ-domain containing polypeptide.

It is noted that Applicant asserts that the Examiner suggested to amend the claim 23 to focus on the method of determining an interaction profile for a PL protein against an arrays of PDZ-domain polypeptide.

The Examiner acknowledge that during the interview on 12/02/03, it was agreed that said amendment would be sufficient to overcome the rejection under 35 U.S.C. 103 (a) as being unpatentable over Gee et al., in view of the known fact disclosed in the Specification on page 53 and further in view of the Coligam et al. However, it was explicitly explained to the Applicant that the amendment should not introduce a new matter and that the amendment must have a clear support in the Specification and Claims as originally filed.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.  
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April 5, 2004

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